IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC., Plaintiffs, v. CONOR MEDSYSTEMS, INC., Defendant.	C.A. No. 05-768-SLR REDACTED

APPENDIX OF EXHIBITS CITED IN ANSWERING BRIEF IN OPPOSITION TO CONOR'S MOTION FOR SUMMARY JUDGMENT OF OBVIOUSNESS

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Dated: May 25, 2007

EXHIBIT 1

- VOLUME B -

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

BOSTON SCIENTIFIC CORPORATION, : CIVIL ACTION
Plaintiff :
vs. :
CORDIS CORPORATION and JOHNSON & JOHNSON, INC., :
Defendants : NO. 03-27 (SLR)

BOSTON SCIENTIFIC SCIMED, INC., and BOSTON SCIENTIFIC CORPORATION, : CIVIL ACTION
Plaintiffs :
vs. :
CORDIS CORPORATION and JOHNSON & JOHNSON, INC., :
Defendants : NO. 03-283 (SLR)

- - -

Wilmington, Delaware
Wednesday, June 22, 2005
9:22 o'clock, a.m.

- - -

BEFORE: HONORABLE SUE L. ROBINSON, Chief Judge, and a jury

- - -

Valerie J. Cunning and
Leonard A. Dibbs,
Official Court Reporters

APPEARANCES:

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-and-

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- - -

PROCEEDINGS

(Proceedings commenced at 9:22 a.m.)

MR. DISKANT: Your Honor, I appreciate your hearing us early this morning. And I think many of our issues have gotten resolved.

I think we can identify the ones that have been resolved quickly on the record and I will get to what the problems are.

I gather Mr. DeLucia has told me he will not make arguments in opening about supposed lack of supply or capacity problems at Cordis, that he will not talk about Cordis profit margins, that he will not talk about so-called adulterated stents and that he will not talk about willfulness issues in this case.

Mr. Desmarais has given me a similar representation, except that he will say that Dr. Jang I think met with Cordis sometime before BX Velocity design was finalized. Assuming that's where he stays, that's fine.

So those are the agreements.

The two issues I think that remain, let me try an easier one first.

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THE COURT: Absolutely.
(Notebooks handed to the witness and the Court.)
BY MS. GARDNER:
Q. Dr. Dawkins, could you turn to Exhibit 687 in the binder that has been provided to you and identify that document for us?
A. Yes. That's my curriculum vitae, which documents my training and papers and so on.
MS. GARDNER: Your Honor, we offer Dr. Dawkins' CV and offer Dr. Dawkins as an expert in the field of interventional cardiology.
MR. DISKANT: No objection.
THE COURT: Thank you.
DEPUTY CLERK: So marked.
*** (Exhibit No. 687 was received into evidence.)
BY MS. GARDNER:
Q. Dr. Dawkins, can you generally explain what coronary artery disease is? We've heard a little bit about it today, but we would appreciate some illustration, if you could provide that.
A. Yes I think in order for me to explain that, it would be helpful to the members of the jury just to deal with a very little simple heart anatomy, which is shown on this slide.

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The main pumping chamber of the heart is here. This rejects blood. The heart muscle itself needs its own blood supply and that's obtained from the coronary arteries, the right coronary artery here and the left coronary artery that goes in two major branches, down the front of the heart and the back of the heart.
If I could have the next slide...
Coronary heart disease or coronary artery disease results from a narrowing, usually a discrete narrowing, due to a buildup of fatty material.
If we could have the next slide...
This fatty material or plaque gradually accumulates or in some people rapidly accumulates so it impedes blood flow down the coronary artery, so the heart muscle can't obtain enough blood and the person will experience angina.
If this blocks completely, then the heart muscle downstream from the blockage dies and the patient would experience a heart attack. And in the United States, approximately 700,000 people a year die from heart disease. It's still the commonest cause of death, more common than cancer.
Q. Prior to about the 1970's, what was the primary treatment for coronary heart disease?

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So it truly acts as a bypass
The patient usually then spends a day or two in Intensive Care, five to seven days in the hospital and, depending on their job, is off work for eight to ten weeks.
So it's a very major procedure.
Q Are there additional complications associated with surgery?
A. Yes. There may well be. Even today, some patients don't survive the procedure and other major complications which everybody is concerned about, which are sometimes unpredictable, are stroke, which happens in a small number of patients, chest infection or pneumonia, or infection of the incisions, either in the leg or in the chest.
Q. Did a treatment option become available at a certain point in time to avoid the complications with coronary artery bypass surgery?
A. Yes. In 1977, a Swiss cardiologist, Andreas Gruentzig, came up with the idea of using very small balloons to stretch out these areas of narrowing in the heart. In fact, he used, as you heard earlier today, Schneider balloons in his very first series of patients. And this had an attraction, of course, of being a minimally-invasive technique compared with cardiac

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surgery. And he developed the ideas and treated the first patients with what became known as balloon angioplasty.
Q. Okay. And do you have with you today something to illustrate balloon angioplasty for the jury?
A. Yes. If we could look at the first schematic here, what we've done here is to take out the coronary artery and lay it out, as you've seen previously from the heart slide.
And in the coronary artery, the blood is flowing down the lumen through the center of the coronary artery.
And you can see here that there's a narrow plaque, a buildup of fatty material.
The operator under local anesthetic inserts a very fine guide wire through a catheter, through a tube, in the local artery. I say to patients this should be a little more discomfort than going to the dentist. It should be less discomfort than going to the dentist. And this puts it in perspective in relation to coronary artery surgery.
So this wire is manipulated down the artery under X-ray control.
And the next slide.
A small balloon is slid down the wire. The

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balloon is expanded and splits and pushes the plugged material into the wall. The balloon and the wire is then removed and the lumen is increased, the blood flow is increased and the patient's symptoms of angina result.
Q. After angioplasty became a commonly-used procedure, were there problems that developed with that procedure?
A. Yes. The attraction of angioplasty was it was a minimally-invasive anesthetic material. There were problems. There were two types of problems. There were early problems and late problems.
The next slide shows the early problem, which was elastic recoil.
So once the balloon was removed, there was a tendency for the plaque material to come back and for the artery to shrink back. So although there was a narrowing that was tighter before, this narrowing could come back in a significant portion of patients.
The other early complication, which was much more devastating and much more predictable was one of dissection.
That is one of these cracks expanded and a section of the wall of the artery fell into the artery lumen and you could see the blood is coming down here and this dissection prevents flow and the blood down

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here is absent.
This could result in heart attack, the need for an urgent emergency bypass operation, or sometimes even death.
And the other Achilles heel of coronary artery was a leg problem, one of restenosis.
If you could click on restenosis...
This occurred after a few weeks or months, when the body reacted to the trauma the balloon had caused by this process that you've already heard about today of neointimal proliferation.
You could liken this to a scar formation when you cut yourself. If you cut yourself, the cut heals. But occasionally, you get a big scar, where the healing process is excessive for the size of the cut. This is what occurred here. This occurred in 20 to 30 percent of patients after balloon angioplasty.
Q. And what sort of problem did this present to a patient after balloon angioplasty?
A. Well, the patient had initially got better. They had no symptoms. The angina went, but then after a few weeks, they develop the same symptoms all over again.
So they either had to go through the same procedure again, possibly with the same outcome, or they had to be considered for coronary artery surgery,

which was obviously a limitation of the technique.

- - -

Q. Were there any efforts to make additional innovations to address the problem of the vessel closure and other problems that you mentioned with balloon angioplasty?

A. Well, there were huge efforts by all the medical device industry, interventional cardiologists, other people with an interest in the field. A number of things were tried.

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EXHIBITS 2-3

REDACTED IN FULL

EXHIBIT 4

US005514154A

United States Patent [19]

Lau et al.

[11] Patent Number: 5,514,154

[45] Date of Patent: May 7, 1996

[54] **EXPANDABLE STENTS**

[75] Inventors: **Lilip Lau**, Sunnyvale; **William M. Hartigan**, Fremont; **John J. Frantzen**, Copperopolis, all of Calif.

[73] Assignee: **Advanced Cardiovascular Systems, Inc.**, Santa Clara, Calif.

[21] Appl. No.: **281,790**

[22] Filed: **Jul. 28, 1994**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 164,986, Dec. 9, 1993, abandoned, which is a continuation of Ser. No. 783,558, Oct. 28, 1991, abandoned.

[51] **Int. Cl.**[6] **A61M 29/00**

[52] **U.S. Cl.** **606/195**; 606/194; 606/108; 623/13

[58] **Field of Search** 606/191–198, 606/108; 604/93, 96, 97, 280, 282, 283; 623/1, 11, 12

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,776,337	10/1988	Palmaz	623/1
4,969,458	11/1990	Wiktor	606/194
4,994,071	2/1991	MacGregor	606/194
5,102,417	4/1992	Palmaz	606/195
5,195,984	3/1993	Schatz	606/193
5,356,433	10/1994	Rowland et al.	623/11

Primary Examiner—Christopher A. Bennett

Attorney, Agent, or Firm—Fulwider Patton Lee & Utecht

[57] **ABSTRACT**

The invention is directed to an expandable stent for implantation in a body lumen, such as an artery, and a method for making it from a single length of tubing. The stent consists of a plurality of radially expandable cylindrical elements generally aligned on a common axis and interconnected by one or more interconnective elements. The individual radially expandable cylindrical elements consist of ribbon-like material disposed in an undulating pattern. Portions of the expanded stent project outwardly into engagement with the vessel wall to more securely attach the stent.

23 Claims, 4 Drawing Sheets

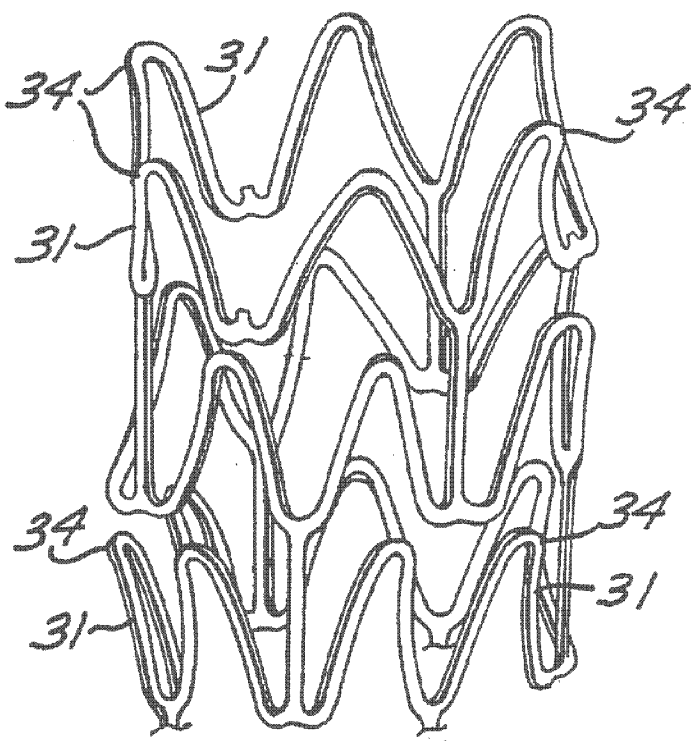


FIG. 1

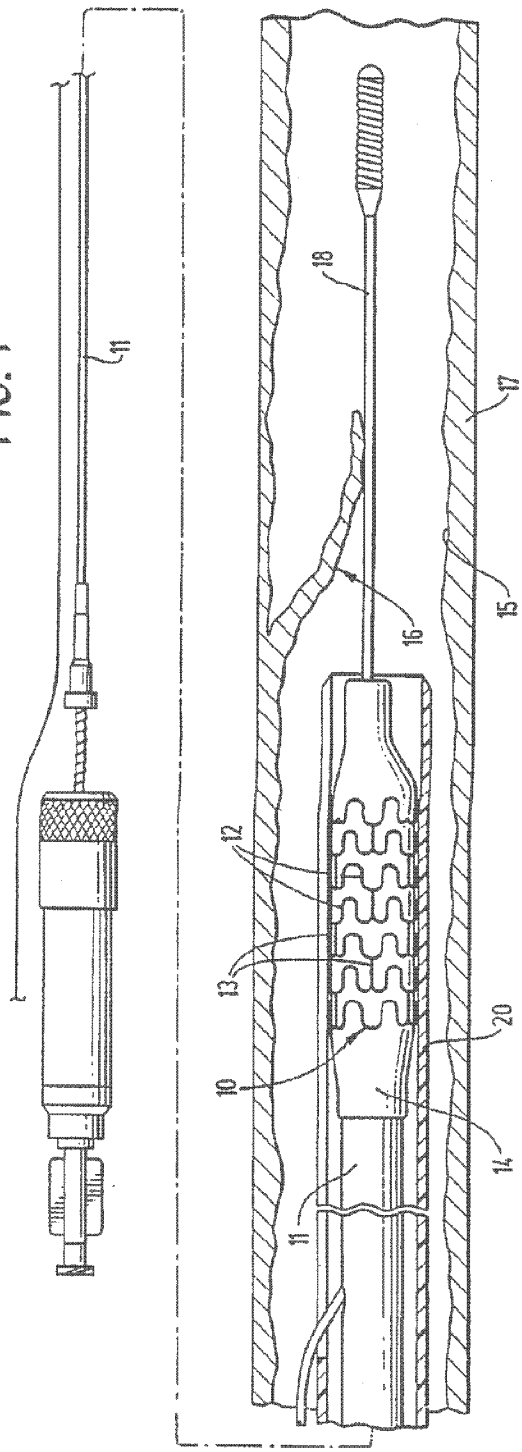


FIG. 3

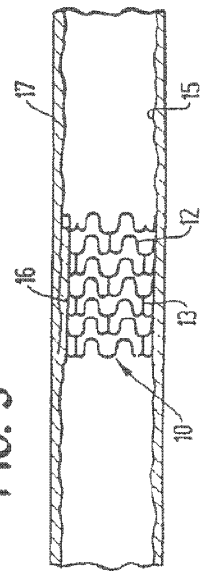


FIG. 2

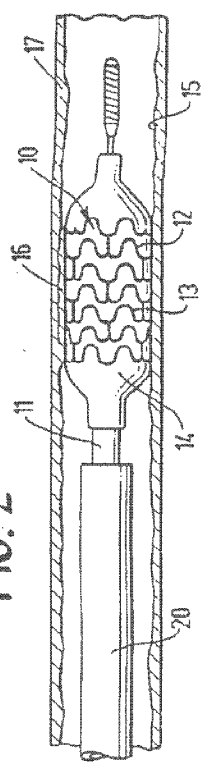


FIG. 4

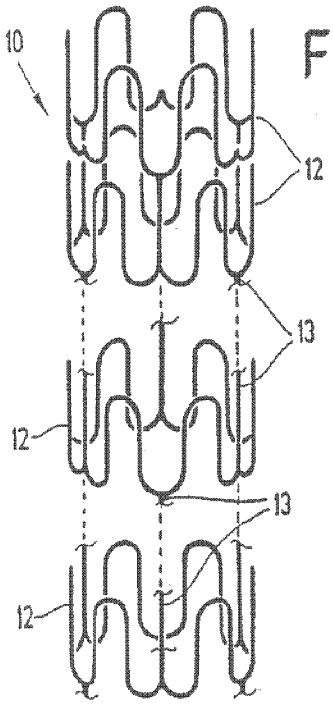


FIG. 6

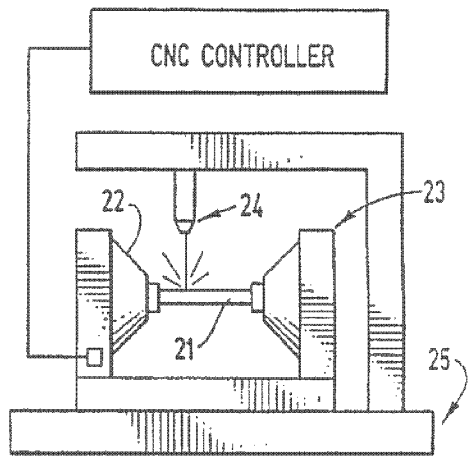


FIG. 5

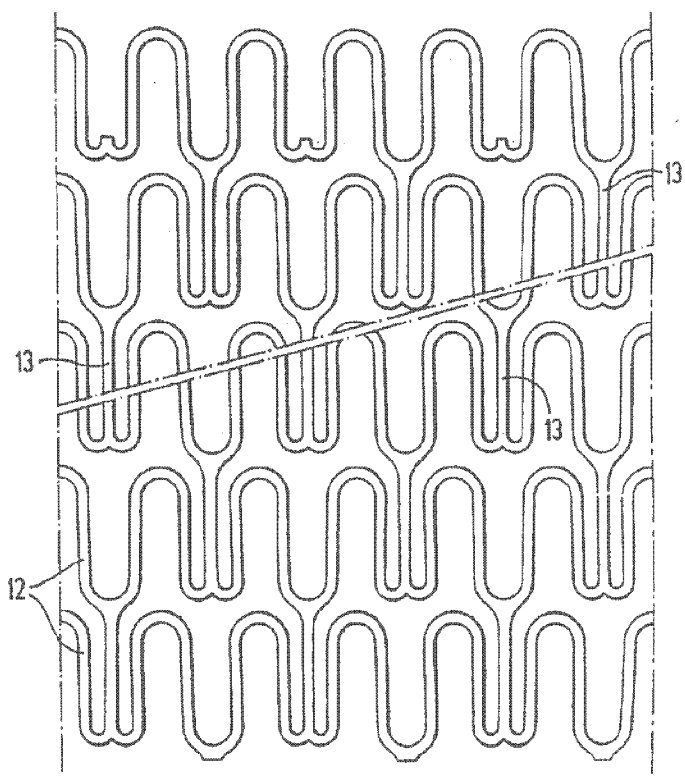


FIG. 7

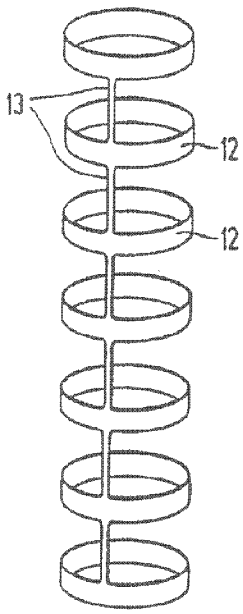


FIG. 8

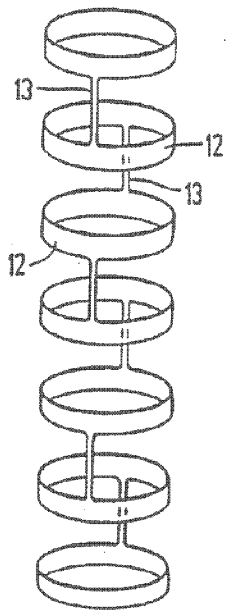


FIG. 9

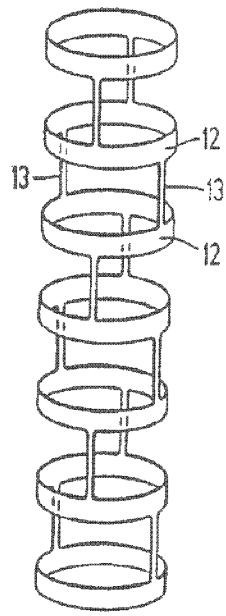


FIG. 10

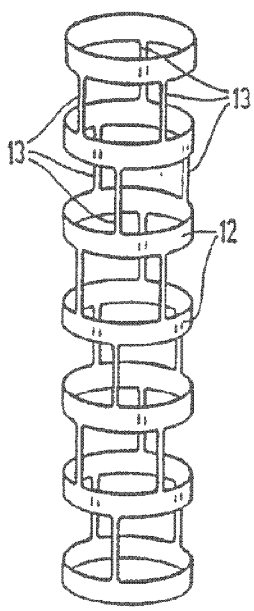
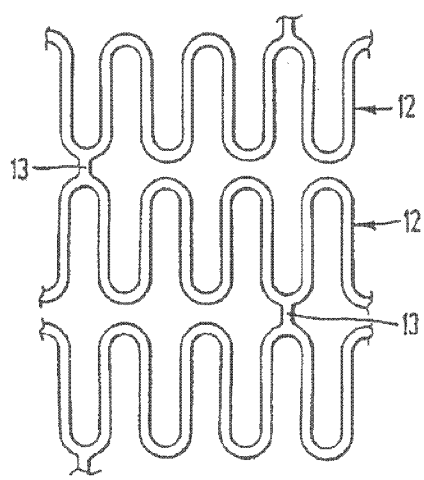


FIG. 11



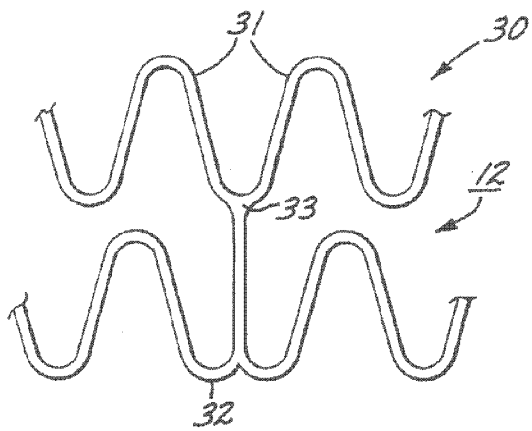


FIG. 12

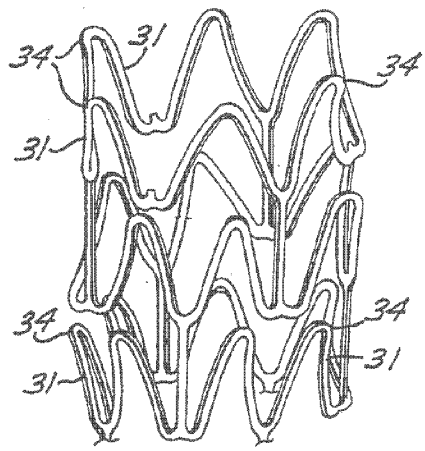


FIG. 13

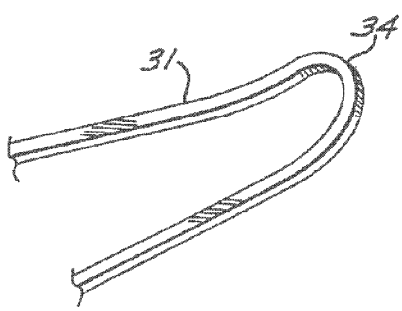


FIG. 14

EXPANDABLE STENTS

RELATED APPLICATIONS

This application is a continuation-in-part of U.S. patent application U.S. Ser. No. 08/164,986 filed Dec. 9, 1993, now abandoned, which is a continuation application of U.S. Ser. No. 07/783,558 filed Oct. 28, 1991, now abandoned.

BACKGROUND OF THE INVENTION

This invention relates to expandable endoprosthesis devices, generally called stents, which are adapted to be implanted into a patient's body lumen, such as blood vessel, to maintain the patency thereof. These devices are very useful in the treatment of atherosclerotic stenosis in blood vessels.

Stents are generally tubular-shaped devices which function to hold open a segment of a blood vessel or other anatomical lumen. They are particularly suitable for use to support and hold back a dissected arterial lining which can occlude the fluid passageway therethrough.

Further details of prior art stents can be found in U.S. Pat. No. 3,868,956 (Alfidi et al.); U.S. Pat. No. 4,512,338 (Balko et al.); U.S. Pat. No. 4,553,545 (Maass et al.); U.S. Pat. No. 4,733,665 (Palmaz); U.S. Pat. No. 4,762,128 (Rosenbluth); U.S. Pat. No. 4,800,882 (Gianturco); U.S. Pat. No. 4,856,516 (Hillstead); and U.S. Pat. No. 4,886,062 (Wiktor), which are hereby incorporated herein in their entirety by reference thereto.

Various means have been described to deliver and implant stents. One method frequently described for delivering a stent to a desired intraluminal location includes mounting the expandable stent on an expandable member, such as a balloon, provided on the distal end of an intravascular catheter, advancing the catheter to the desired location within the patient's body lumen, inflating the balloon on the catheter to expand the stent into a permanent expanded condition and then deflating the balloon and removing the catheter. One of the difficulties encountered using prior stents involved maintaining the radial rigidity needed to hold open a body lumen while at the same time maintaining the longitudinal flexibility of the stent to facilitate its delivery.

What has been needed and heretofore unavailable is a stent which has a high degree of flexibility so that it can be advanced through tortuous passageways and can be readily expanded and yet have the mechanical strength to hold open the body lumen into which it expanded. The present invention satisfies this need.

SUMMARY OF THE INVENTION

The present invention is directed to an expandable stent which is relatively flexible along its longitudinal axis to facilitate delivery through tortuous body lumens, but which is stiff and stable enough radially in an expanded condition to maintain the patency of a body lumen such as an artery when implanted therein.

The stent of the invention generally includes a plurality of radially expandable cylindrical elements which are relatively independent in their ability to expand and to flex relative to one another. The individual radially expandable cylindrical elements of the stent are dimensioned so as to be longitudinally shorter than their own diameters. Interconnecting elements or struts extending between adjacent cylindrical elements provide increased stability and a preferable position to prevent warping of the stent upon the expansion thereof. The resulting stent structure is a series of radially expandable cylindrical elements which are spaced longitudinally close enough so that small dissections in the wall of a body lumen may be pressed back into position against the lumenal wall, but not so close as to compromise the longitudinal flexibilities of the stent. The individual cylindrical elements may rotate slightly relative to adjacent cylindrical elements without significant deformation, cumulatively giving a stent which is flexible along its length and about its longitudinal axis but is still very stiff in the radial direction in order to resist collapse.

The stent embodying features of the invention can be readily delivered to the desired lumenal location by mounting it on an expandable member of a delivery catheter, for example a balloon, and passing the catheter-stent assembly through the body lumen to the implantation site. A variety of means for securing the stent to the expandable member on the catheter for delivery to the desired location are available. It is presently preferred to compress the stent onto the balloon. Other means to secure the stent to the balloon include providing ridges or collars on the inflatable member to restrain lateral movement, or using bioresorbable temporary adhesives.

The presently preferred structure for the expandable cylindrical elements which form the stents of the present invention generally circumferential undulating pattern, e.g. serpentine. The transverse cross-section of the undulating component of the cylindrical element is relatively small and preferably has an apect ratio of about two to one to about 0.5 to one. A one to one aspect ratio has been found particularly suitable. The open reticulated structure of the stent allows for the perfusion of blood over a large portion of the arterial wall which can improve the healing and repair of a damaged arterial lining.

The radial expansion of the expandable cylinder deforms the undulating pattern thereof similar to changes in a waveform which result from decreasing the waveform's amplitude and the frequency. Preferably, the undulating patterns of the individual cylindrical structures are in phase with each other in order to prevent the contraction of the stent along its length when it is expanded. The cylindrical structures of the stent are plastically deformed when expanded (except with NiTi alloys) so that the stent will remain in the expanded condition and, therefore, they must be sufficiently rigid when expanded to prevent the collapse thereof in use. During expansion of the stent, portions of the undulating pattern will tip outwardly resulting in projecting members on the outer surface of the expanded stent. These projecting members tip radially outwardly from the outer surface of the stent and embed in the vessel wall and help secure the expanded stent so that it does not move once it is implanted.

With superelastic NiTi alloys, the expansion occurs when the stress of compression is removed so as to allow the phase transformation from austenite back to martensite and as a result the expansion of the stent.

The elongated elements which interconnect adjacent cylindrical elements should have a transverse cross-section similar to the transverse dimensions of the undulating components of the expandable cylindrical elements. The interconnecting elements may be formed in a unitary structure with the expandable cylindrical elements from the same intermediate product, such as a tubular element, or they may be formed independently and connected by suitable means, such as by welding or by mechanically securing the ends of the interconnecting elements to the ends of the expandable cylindrical elements. Preferably, all of the interconnecting

elements of a stent are joined at either the peaks or the valleys of the undulating structure of the cylindrical elements which for the stent. In this manner there is no shortening of the stent upon expansion.

The number and location of elements interconnecting adjacent cylindrical elements can be varied in order to develop the desired longitudinal flexibility in the stent structure both in the unexpanded as well as the expanded condition. These properties are important to minimize alteration of the natural physiology of the body lumen into which the stent is implanted and to maintain the compliance of the body lumen which is internally supported by the stent. Generally, the greater the longitudinal flexibility of the stent, the easier and the more safely it can be delivered to the implantation site.

In a presently preferred embodiment of the invention the stent is conveniently and easily formed by coating stainless steel tubing with a material resistant to chemical etching, removing portions of the coating to expose portions of underlying tubing which are to be removed to develop the desired stent structure. The exposed portions of the tubing are removed by chemically etching from the tubing exterior leaving the coated portion of the tubing material in the desired pattern of the stent structure. The etching process develops smooth openings in the tubing wall without burrs or other artifacts which are characteristic of mechanical or laser machining processes in the small sized products contemplated. Moreover, a computer controlled laser patterning process to remove the chemical resistive coating makes photolithography technology adaptable to the manufacture of these small products. The forming of a mask in the extremely small sizes needed to make the small stents of the invention would be a most difficult task. A plurality of stents can be formed from one length of tubing by repeating the stent pattern and providing small webs or tabs to interconnect the stents. After the etching process, the stents can be separated by severing the small webs or tabs which connect them.

Other features and advantages of the present invention will become more apparent from the following detailed description of the invention. When taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an elevational view, partially in section, of a stent embodying features of the invention which is mounted on a delivery catheter and disposed within a damaged artery.

FIG. **2** is an elevational view, partially in section, similar to that shown in FIG. **1** wherein the stent is expanded within a damaged artery, pressing the damaged lining against the arterial wall.

FIG. **3** is an elevational view, partially in section showing the expanded stent within the artery after withdrawal of the delivery catheter.

FIG. **4** is a perspective view of a stent embodying features of the invention in an unexpanded state, with one end of the stent being shown in an exploded view illustrate the details thereof.

FIG. **5** is a plan view of a flattened section of a stent of the invention which illustrates the undulating pattern of the stent shown in FIG. **4**.

FIG. **6** is a schematic representation of equipment for selectively removing coating applied to tubing in the manufacturing of the stents of the present invention.

FIGS. **7** through **10** are perspective views schematically illustrating various configurations of interconnective element placement between the radially expandable cylindrical elements of the stent.

FIG. **11** is a plan view of a flattened section of a stent illustrating an alternate undulating pattern in the expandable cylindrical elements of the stent which are out of phase.

FIG. **12** is an enlarged partial view of the stent of FIG. **5** with the various members slightly expanded.

FIG. **13** is a perspective view of the stent of FIG. **4** after it is fully expanded depicting some members projecting radially outwardly.

FIG. **14** is an enlarged, partial perspective view of one U-shaped member with its tip projecting outwardly after expansion.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. **1** illustrates a stent **10** incorporating features of the invention which is mounted onto a delivery catheter **11**. The stent generally comprises a plurality of radially expandable cylindrical elements **12** disposed generally coaxially and interconnected by elements **13** disposed between adjacent cylindrical elements. The delivery catheter **11** has an expandable portion or balloon **14** for expanding of the stent **10** within an artery **15**. The artery **15**, as shown in FIG. **1**, has a dissected lining **16** which has occluded a portion of the arterial passageway.

The delivery catheter **11** onto which the stent **10** is mounted, is essentially the same as a conventional balloon dilatation catheter for angioplasty procedures. The balloon **14** may be formed of suitable materials such as polyethylene, polyethylene terephthalate, polyvinyl chloride, nylon and ionomers such as Surlyn® manufactured by the Polymer Products Division of the Du Pont Company. Other polymers may also be used. In order for the stent **10** to remain in place on the balloon **14** during delivery to the site of the damage within the artery **15**, the stent **10** is compressed onto the balloon. A retractable protective delivery sleeve **20** as described in co-pending applications Ser. No. 07/647,464 filed on Apr. 25, 1990 and entitled STENT DELIVERY SYSTEM may be provided to further ensure that the stent stays in place on the expandable portion of the delivery catheter **11** and prevent abrasion of the body lumen by the open surface of the stent **20** during delivery to the desired arterial location. Other means for securing the stent **10** onto the balloon **14** may also be used, such as providing collars or ridges on the ends of the working portion, i.e. the cylindrical portion, of the balloon.

Each radially expandable cylindrical element **12** of the stent **10** may be independently expanded. Therefore, the balloon **14** may be provided with an inflated shape other than cylindrical, e.g. tapered, to facilitate implantation of the stent **10** in a variety of body lumen shapes.

In a preferred embodiment, the delivery of the stent **10** is accomplished in the following manner. The stent **10** is first mounted onto the inflatable balloon. **14** on the distal extremity of the delivery catheter **11**. The balloon **14** is slightly inflated to secure the stent **10** onto the exterior of the balloon. The catheter-stent assembly is introduced within the patient's vasculature in a conventional Seldinger technique through a guiding catheter (not shown). A guidewire **18** is disposed across the damaged arterial section with the detached or dissected lining **16** and then the catheter-stent assembly is advanced over a guidewire **18** within the artery

15 until the stent 10 is directly under the detached lining 16. The balloon 14 of the catheter is expanded, expanding the stent 10 against the artery 15, which is illustrated in FIG. 2. While not shown in the drawing, the artery 15 is preferably expanded slightly by the expansion of the stent 10 to seat or otherwise fix the stent 10 to prevent movement. In some circumstances during the treatment of stenotic portions of an artery, the artery may have to be expanded considerably in order to facilitate passage of blood or other fluid therethrough.

The stent 10 serves to hold open the artery 15 after the catheter 11 is withdrawn, as illustrated by FIG. 3. Due to the formation of the stent 10 from elongated tubular member, the undulating component of the cylindrical elements of the stent 10 is relatively flat in transverse cross-section, so that when the stent is expanded, the cylindrical elements are pressed into the wall of the artery 15 and as a result do not interfere with the blood flow through the artery 15. The cylindrical elements 12 of stent 10 which are pressed into the wall of the artery 15 will eventually be covered with endothelial cell growth which further minimizes blood flow interference. The undulating portion of the cylindrical sections 12 provide good tacking characteristics to prevent stent movement within the artery. Furthermore, the closely spaced cylindrical elements 12 at regular intervals provide uniform support for the wall of the artery 15, and consequently are well adapted to tack up and hold in place small flaps or dissections in the wall of the artery 15 as illustrated in FIGS. 2 and 3.

FIG. 4 is an enlarged perspective view of the stent 10 shown in FIG. 1 with one end of the stent shown in an exploded view to illustrate in greater detail the placement of interconnecting elements 13 between adjacent radially expandable cylindrical elements 12. Each pair of the interconnecting elements 13 on one side of a cylindrical element 12 are preferably placed to achieve maximum flexibility for a stent. In the embodiment shown in FIG. 4 the stent 10 has three interconnecting elements 13 between adjacent radially expandable cylindrical elements 12 which are 120 degrees apart. Each pair of interconnecting elements 13 on one side of a cylindrical element 12 are offset radially 60 degrees from the pair on the other side of the cylindrical element. The alternation of the interconnecting elements results in a stent which is longitudinally flexible in essentially all directions. Various configurations for the placement of interconnecting elements are possible, and several examples are illustrated schematically in FIGS. 7–10. However, as previously mentioned, all of the interconnecting elements of an individual stent should be secured to either the peaks or valleys of the undulating structural elements in order to prevent shortening of the stent during the expansion thereof.

FIG. 10 illustrates a stent of the present invention wherein three interconnecting elements 12 are disposed between radially expandable cylindrical elements 11. The interconnecting elements 12 are distributed radially around the circumference of the stent at a 120-degree spacing. Disposing four or more interconnecting elements 13 between adjacent cylindrical elements 12 will generally give rise to the same considerations discussed above for two and three interconnecting elements.

The properties of the stent 10 may also be varied by alteration of the undulating pattern of the cylindrical elements 13. FIG. 11 illustrates an alternative stent structure in which the cylindrical elements are in serpentine patterns but out of phase with adjacent cylindrical elements. The particular pattern and how many undulations per unit of length around the circumference of the cylindrical element 13, or the amplitude of the undulations, are chosen to fill particular mechanical requirements for the stent such as radial stiffness.

The number of undulations may also be varied to accommodate placement of interconnecting elements 13, e.g. at the peaks of the undulations or along the sides of the undulations as shown in FIGS. 5 and 11.

In keeping with the invention, and with reference to FIGS. 4 and 12–14, cylindrical elements 12 are in the form of a serpentine pattern 30. As previously mentioned, each cylindrical element 12 is connected by interconnecting elements 13. Serpentine pattern 30 is made up of a plurality of U-shaped members 31, W-shaped members 32, and Y-shaped members 33, each having a different radius so that expansion forces are more evenly distributed over the various members.

As depicted in FIGS. 13 and 14, after cylindrical elements 12 have been radially expanded, outwardly projecting edges 34 are formed. That is, during radial expansion U-shaped members 31 will tip outwardly thereby forming outwardly projecting edges. These outwardly projecting edges provide for a roughened outer wall surface of stent 10 and assist in implanting the stent in the vascular wall by embedding into the vascular wall. In other words, outwardly projecting edges embed into the vascular wall, for example artery 15, as depicted in FIG. 3. Depending upon the dimensions of stent 10 and the thickness of the various members making up the serpentine pattern 30, any of the U-shaped members 31, W-shaped members 32, and Y-shaped members 33 can tip radially outwardly to form a projecting edge 34. It is most likely and preferred that U-shaped members 31 tip outwardly since they do not join with any connecting member 13 to prevent them from expanding outwardly.

The stent 10 of the present invention can be made in many ways. However, the preferred method of making the stent is to coat a thin-walled tubular member, such as stainless steel tubing, with a material which is resistive to chemical etchants, remove portions of the coating to expose underlying tubing which is to be removed but to leave coated portions of the tubing in the desired pattern for the stent so that subsequent etching will remove the exposed portions of the metallic tubing, but will leave relatively untouched the portions of the metallic tubing which are to form the stent. The coated portion of the metallic tube is in the desired shape for the stent. An etching process avoids the necessity of removing burrs or slag inherent in conventional or laser machining process. It is preferred to remove the etchant-resistive material by means of a machine-controlled laser as illustrated schematically in FIG. 6.

A coating is applied to a length of tubing which, when cured, is resistive to chemical etchants. "Blue Photoresist" made by the Shipley Company in San Jose, Calif., is an example of suitable commercially available photolithographic coatings. The coating is preferably applied by electrophoretic deposition.

To ensure that the surface finish is reasonably uniform, one of the electrodes used for the electrochemical polishing is a doughnut-shaped electrode which is placed about the central portion of the tubular member.

The tubing may be made of suitable biocompatible material such as stainless steel, titanium, tantalum, superelastic NiTi alloys and even high strength thermoplastic polymers. The stent diameter is very small, so the tubing from which it is made must necessarily also have a small diameter. Typically the stent has an outer diameter on the order of about 0.06 inch in the unexpanded condition, the same outer

diameter of the tubing from which it is made, and can be expanded to an outer diameter of 0.1 inch or more. The wall thickness of the tubing is about 0.003 inch. In the instance when the stent was plastic, it would have to be heated within the arterial site where the stent is expanded to facilitate the expansion of the stent. Once expanded, it would then be cooled to retain its expanded state. The stent may be conveniently heated by heating the fluid within the balloon or the balloon directly by a suitable system such as disclosed in a co-pending application Ser. No. 07/521,337, filed Jan. 26, 1990 entitled DILATATION CATHETER ASSEMBLY WITH HEATED BALLOON which is incorporated herein in its entirety by reference. The stent may also be made of materials such as superelastic NiTi alloys such as described in co-pending application Ser. No. 07/629,381, filed Dec. 18, 1990, entitled SUPERELASTIC GUIDING MEMBER which is incorporated herein in its entirety by reference. In this case the stent would be formed full size but deformed (e.g. compressed) into a smaller diameter onto the balloon of the delivery catheter to facilitate transfer to a desired intraluminal site. The stress induced by the deformation transforms the stent from a martensite phase to an austenite phase and upon release of the force, when the stent reaches the desired intraluminal location, allows the stent to expand due to the transformation back to the martensite phase.

Referring to FIG. **6**, the coated tubing **21** is put in a rotatable collet fixture **22** of a machine controlled apparatus **23** for positioning the tubing **21** relative to a laser **24**. According to machine-encoded instructions, the tubing **21** is rotated and moved longitudinally relative to the laser **24** which is also machine controlled. The laser selectively removes the etchant-resistive coating on the tubing by ablation and a pattern is formed such that the surface of the tube that is to be removed by a subsequent chemical etching process is exposed. The surface of the tube is therefore left coated in the discrete pattern of the finished stent.

A presently preferred system for removing the coating on the tubing includes the use of an 80-watt CO_2 laser, such as a Coherent Model 44, in pulse mode (0.3 mS pulse length); 48 mA key current and 48 W key power with 0.75 W average power, at 100 Hz; Anorad FR=20; 12.5 Torr; with no assist gas. Low pressure air is directed through the fine focus head to ensure that no vapor contacts the lens. The assist gas jet assembly on the laser unit may be removed to allow a closer proximity of the fine focus head and the collet fixture. Optimum focus is set at the surface of the tubing. Cured photo-resist coating readily absorbs the energy of the CO_2 wavelength, so that it can be readily removed by the laser. A coated 4-inch length of 0.06 inch stainless steel tubing is preferred and four stents can be patterned on the length of tubing. Three tabs or webs between stents provide good handling characteristics for the tubing after the etching process.

The process of patterning the resistive coating on the stent is automated except for loading and unloading the length of tubing. Referring again to FIG. **6** it may be done, for example, using a CNC-opposing collet fixture **22** for axial rotation of the length of tubing, in conjunction with a CNC X/Y table **25** to move the length of tubing axially relative to a machine-controlled laser as described. The entire space between collets can be patterned using the CO_2 laser set-up of the foregoing example. The program for control of the apparatus is dependent on the particular configuration used and the pattern to be ablated in the coating, but is otherwise conventional.

This process makes possible the application of present photolithography technology in manufacturing the stents. While there is presently no practical way to mask and expose a tubular photo-resist coated part of the small size required for making intravascular stents, the foregoing steps eliminate the need for conventional masking techniques.

After the coating is thus selectively ablated, the tubing is removed from the collet fixture **22**. Next, wax such at ThermoCote N-4 is heated to preferably just above its melting point, and inserted into the tubing under vacuum or pressure. After the wax has solidified upon cooling, it is reheated below its melting point to allow softening, and a smaller diameter stainless steel shaft is inserted into the softened wax to provide support. The tubing is then etched chemically in a conventional manner. After cutting the tabs connecting the stents any surface roughness or debris from the tabs is removed. The stents are preferably electrochemically polished in an acidic aqueous solution such as a solution of ELECTRO-GLO #300, sold by the ELECTRO-GLO CO., Inc. in Chicago, Ill., which is a mixture of sulfuric acid, carboxylic acids, phosphates, corrosion inhibitors and a biodegradable surface active agent. The bath temperature is maintained at about 110–135 degrees F. and the current density is about 0.4 to about 1.5 amps per $in.^2$ Cathode to anode area should be at least about two to one. The stents may be further treated if desired, for example by applying a biocompatible coating.

While the invention has been illustrated and described herein in terms of its use as an intravascular stent, it will be apparent to those skilled in the art that the stent can be used in other instances such as to expand prostatic urethras in cases of prostate hyperplasia. Other modifications and improvements may be made without departing from the scope of the invention.

Other modifications and improvements can be made to the invention without departing from the scope thereof.

What is claimed is:

1. A longitudinally flexible stent for implanting in a body lumen, comprising:

a plurality of cylindrical elements which are independently expandable in the radial direction and which are interconnected so as to be generally aligned on a common longitudinal axis;

a plurality of connecting elements for interconnecting said cylindrical elements, said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other; and

an outer wall surface on said cylindrical elements, said outer wall surface being smooth prior to expansion of said stent and forming a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter.

2. The stent of claim **1**, wherein said outer wall surface is substantially smooth when said stent in said first diameter configuration and said outwardly projecting edges form only as said stent is expanded radially outwardly from said first diameter to said second, enlarged diameter.

3. The stent of claim **1**, wherein said plurality of outwardly projecting edges extend radially outwardly from said outer wall surface and embed in the vascular wall of the body lumen in order to more firmly attach said stent to the vascular wall.

4. The stent of claim **1**, wherein said plurality of cylindrical elements include a plurality of peaks and valleys having a serpentine pattern.

5. The stent of claim **4**, wherein said plurality of peaks and valleys include a plurality of U-shaped members, a plurality

of Y-shaped members, and a plurality of W-shaped members, whereby a portion of said Y-shaped members forms said plurality of said connecting elements.

6. The stent of claim 5, wherein at least some of said plurality of said U-shaped members tip radially outwardly to form said outwardly projecting edges upon radial expansion of said stent.

7. The stent of claim 5, wherein at least some of said plurality of U-shaped, W-shaped, and Y-shaped members tip radially outwardly to form said outwardly projecting edges upon radial expansion of said stent.

8. The stent of claim 1, wherein said cylindrical elements are capable of retaining their expanded condition upon the expansion thereof.

9. The stent of claim 1, wherein said stent is formed of a biocompatible material selected from the group of materials consisting of stainless steel, tantalum, NiTi alloys, and thermoplastic polymers.

10. The stent of claim 1, wherein said stent is formed from a single piece of tubing.

11. The stent of claim 1, wherein said stent is coated with a biocompatible coating.

12. A longitudinally flexible stent, comprising:

a plurality of cylindrical elements which are independently expandable in the radial direction and which are interconnected so as to be concentrically aligned on a common longitudinal axis; and

a plurality of generally parallel connecting elements for interconnecting said cylindrical elements, said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other, so that said stent, when expanded radially outwardly, retains its overall length without appreciable shortening.

13. The stent of claim 12, wherein said cylindrical elements are capable of retaining their expanded condition upon the expansion thereof.

14. The stent of claim 12, wherein said radially expandable cylindrical elements in an expanded condition have a length less than the diameter thereof.

15. The stent of claim 14, wherein said stent is formed of a biocompatible material selected from the group consisting of stainless steel, tantalum, super-elastic NiTi alloys, and thermoplastic polymers.

16. The stent of claim 12, wherein said connecting elements between adjacent cylindrical elements are in axial alignment.

17. The stent of claim 12, wherein said connecting elements between adjacent cylindrical elements are circumferentially displaced with respect to said longitudinal axis.

18. The stent of claim 17, wherein the circumferential displacement of said connecting elements between adjacent cylindrical elements is uniform.

19. The stent of claim 12, wherein there are up to four of said connecting elements disposed between adjacent radially expandable cylindrical elements.

20. The stent of claim 12, wherein said radially expandable cylindrical elements and said connecting elements are made of the same material.

21. The stent of claim 12, wherein said stent is formed from a single piece of tubing.

22. The stent of claim 12, wherein the stent is coated with a biocompatible coating.

23. A longitudinally flexible stent for implanting in a body lumen, comprising:

a plurality of cylindrical elements which are independently expandable in the radial direction and which are interconnected so as to be generally aligned on a common longitudinal axis;

a plurality of connecting elements for interconnecting said cylindrical elements, said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other;

an outer wall surface on said cylindrical elements, said outer wall surface having a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter, whereby said stent does not substantially shorten upon expansion from said first diameter to said second, larger diameter.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,514,154
DATED : May 7, 1996
INVENTOR(S) : Lilip Lau, William M. Hartigan, John J. Frantzen

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 3, Line 3, Change "for", To read --form--.

Column 3, Line 41, Change "invention. When", To read --invention, when--.

Column 4, Line 46, Change "20", To read --10--.

Column 5, Line 53 and Line 55, Change "12", To read --13--.

Column 5, Line 54, Change "11", To read --12--.

Column 5, Line 63 and Line 67, Change "13", To read --12--.

Column 8, Line 33, Remove entire paragraph that begins with "Other".

Signed and Sealed this

Twenty-fourth Day of March, 1998

Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks